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09/954,574	09/14/2001	Thomas D. Lyster	US010599	7222

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT PAPER NUMBER

3762

DATE MAILED: 04/06/2004

11

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/954,574

Applicant(s)

LYSTER ET AL.

Examiner

George R Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-13 and 15-23 is/are pending in the application.
- 4a) Of the above claim(s) 19-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7-13 and 15-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4, 7.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 19-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Applicant's election with traverse of the restriction in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the amended claims are not restrictable. This is not found persuasive because the amended claims are still restrictable.

The requirement is still deemed proper and is therefore made FINAL.

The inventions are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process not requiring "electronically" determining whether the patient require defibrillation or determining whether the patient is an adult or child, but by the operator determining whether the patient requires defibrillation or having the defibrillator being pre-programmed to operate as a child or adult defibrillator.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1, 3-5, 7-13, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, in the next to last line, "an electrical waveform" is vague and should refer to the "second" waveform since it is used in claim 16.

In claim 5, line 7, "a first electrical waveform" is vague since claim 16 has the first waveform being delivered to the adult. It is suggested to use "the second... waveform".

In claim 8, line 3, "a second electrical waveform" is vague since it is also used in claim 16. It is unclear if this is the same waveform or another waveform. In line 4, "the first... waveform" is vague and should be the "the second... waveform".

In claim 9, "the second... waveform" and "the first... waveform" are vague.

In claim 11, "the first... waveform" is vague.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 16 is rejected under 35 U.S.C. 102(e) as being anticipated by Olson et al (6125298). Olson uses the same electrodes on children and adults (the claimed "universal electrode" shown in figures 3-5 and 8). In addition, Olson shows in figure 8 that the universal

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electrode is removably coupled to the energy modifier or defibrillator system component, 304, to provide the different electrical waveforms.

Claims 1, 5, 16, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Morgan et al (6134468). Morgan states in column 4, line 45 that the electrodes used on children are the electrodes ordinarily used on adults.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 7, 8, 9, 11, 12, 13, 17, and 18 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Olson et al. Olson discloses the increasing energy level shocks in column 9.

In the alternative, Olson discloses the claimed invention except for the particulars energies of the first and second waveforms, and the additional waveform energies of the second

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waveform (claims 1, 5, 8, 9, 11-13, 17, and 18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pediatric and adult defibrillation method as taught by Olson, with the particulars energies of the first and second waveforms, and the additional waveform energies of the second waveform since it was known in the art that pediatric and adult defibrillation methods use the particulars energies of the first and second waveforms, and the additional waveform energies of the second waveform to provide an effective waveform for defibrillation of adults and children.

Claim 7 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Morgan et al. Morgan states that the defibrillator is an automatic defibrillator and will inherently determine whether defibrillation was successful in order to deliver additional shocks if necessary.

In the alternative, Morgan discloses the claimed invention except for the determination of whether defibrillation was successful. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the automatic defibrillator as taught by Morgan, with a determination of whether defibrillation was successful since it was known in the art that defibrillators determine whether defibrillation was successful in order to deliver additional shocks to stop fibrillation.

Claims 8, 9, 11, 12, 13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan et al. Morgan states that the defibrillator is an automatic defibrillator and will inherently determine whether defibrillation was successful in order to deliver additional shocks if necessary.

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Morgan et al discloses the claimed invention except for the determination of whether defibrillation was successful (claims 8, 9, and 11), the particulars energies of the first and second waveforms, and the additional/incremental waveform energies of the second waveform (claims 8, 9, 11-13, and 17). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pediatric and adult defibrillation method as taught by Morgan, with a determination of whether defibrillation was successful, the particulars energies of the first and second waveforms, and the additional waveform energies of the second waveform since it was known in the art that pediatric and adult defibrillation methods use a determination of whether defibrillation was successful in order to deliver additional shocks to stop fibrillation and since it was known that defibrillators use the particulars energies of the first and second waveforms, and the additional waveform energies of the second waveform to provide an effective waveform for defibrillation of adults and children.

Claims 3, 4, 10, and 15 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Olson et al. Olson uses the same electrodes on children and adults (the claimed "universal electrode"), shown in figures 3-5 and 8, and incorporates by reference three patents, 5697955, 5579919, 5402884, that show the conductive portion 56 with a hole/opening in it being a foil. In addition, it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961).

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In the alternative, Olson discloses the claimed invention except for the conductive portion, 56, being a foil. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrode with conductive portion as taught by Olson, with the conductive portion being a foil since it was known in the art that defibrillation electrodes with conductive portions make the conductive portion out of a foil to provide an inexpensive, light, conductive portion that can easily distribute the defibrillation energy.

Claims 3, 4, 10, and 15 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Morgan et al. It has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961).

In the alternative, Morgan discloses the claimed invention except for the conductive portion of the electrode being a foil with an opening. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrode with conductive portion as taught by Morgan, with the conductive portion being a foil with an opening since it was known in the art that defibrillation electrodes with conductive portions make the conductive portion out of a foil with an opening to provide an inexpensive, light, conductive portion that can easily distribute the defibrillation energy.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.




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Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612.

The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
George R Evanisko  
Primary Examiner  
Art Unit 3762

3/31/4

GRE  
March 31, 2004